DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

94537d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

January 9, 2004

WARNING LETTER

NWE-10-04W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jan E. Smith, President, Co-owner
Bombay Duck Company Ltd.
50 Beharrell Street
Concord, Massachusetts 01742

Dear Ms. Smith:

On October 8-9, 2003 we inspected your seafood processing facility, located in Concord, Massachusetts. We found that you have serious deviations from the Seafood Hazard Analysis Critical Control Points (HACCP) regulation, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or to otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly, your tuna fish sandwiches and shrimp dips have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulation though links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that at a minimum lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21

CFR Part 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, you firm's HACCP plan for Shrimp Dip does not list the food safety hazards of pathogen growth and toxin formation.

The food safety hazards of pathogen growth and toxin formation, which are associated with your Shrimp Dip, may be controlled by ensuring that the dip and raw material ingredients are not exposed to times and temperatures which may be conducive to the growth of pathogenic microorganisms. You may control pathogen growth by monitoring your processing steps (time & temperature) and your storage temperatures using any continuous logging method, or by using a high temperature alarm. You may wish to refer to Chapter 12 of the Fish and Fisheries Products Hazards and Controls Guidance for examples of some of the FDA recommended controls and critical limits.

In addition, if your finished product is heat sealed, Clostridium botulinum may be a likely hazard. FDA recommends that your product have additional barriers in place (i.e., pH of 5 or below; salt 5% or more; or water activity below 0.97) in your finished product, in addition to continuous monitoring of the refrigerated storage temperatures. You may wish to refer to Chapter 13 of the Fish and Fisheries Products Hazards and Controls Guidance for examples of some FDA recommended controls and critical limits.

2. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at any of your critical control points listed in your HACCP plan for Shrimp Dip. Specifically, your firm failed to record temperature observations during the refrigerated storage of your finished product.

3. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably like to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for tuna fish sandwiches to control the food safety hazards of pathogen growth and histamine formation. If your finished sandwiches are enclosed in oxygen impermeable packaging, *Clostridium botulinum* may be an additional hazard to consider.

4. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation control records for seven (7) of the eight (8) areas of sanitation.

We may take further action if you do not promptly correct these violations. For instance, we may seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation, such as a completed HACCP plan, or other useful information that would assist in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulation and the Current Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issues in this letter, please contact Mr. Ota at (781) 596-7762.

Sincerely,

Gail T. Costello
District Director
New England District